**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF MISSOURI**
**EASTERN DIVISION**

ABBVIE INC. (a Delaware corporation); ALLERGAN, INC. (a Delaware corporation); DURATA THERAPEUTICS, INC. (a Delaware corporation); ABBVIE PRODUCTS LLC (a Georgia limited liability company); APTALIS PHARMA US, INC. (a Delaware corporation); PHARMACYCLICS LLC (a Delaware limited liability company); ALLERGAN SALES, LLC (a Delaware limited liability company),

*Plaintiffs*,

v.

ANDREW BAILEY, in his official capacity as ATTORNEY GENERAL OF THE STATE MISSOURI,

and

JAMES L. GRAY, in his official capacity as PRESIDENT OF THE MISSOURI BOARD OF PHARMACY; CHRISTIAN S. TADRUS, in his official capacity as VICE-PRESIDENT OF THE MISSOURI BOARD OF PHARMACY; and DOUGLAS R. LANG, ANITA K. PARRAN, COLBY GROVE, TAMMY THOMPSON, and DARREN HARRIS, in their official capacities as MEMBERS OF THE MISSOURI BOARD OF PHARMACY.

*Defendants*.

**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

Case No. _____

**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

Plaintiffs AbbVie Inc., Allergan, Inc., Durata Therapeutics, Inc., AbbVie Products LLC, Aptalis Pharma US, Inc., Pharmacyclics LLC, Allergan Sales, LLC (collectively "AbbVie" or "Plaintiffs"), by and through their undersigned attorneys, bring this action for declaratory and injunctive relief against the Missouri Attorney General and the President, Vice-President, and Members of the Missouri Board of Pharmacy, challenging the applicability and constitutionality of S.B. No. 751[1] (codified at Mo. Rev. Stat. § 376.414, amending Mo. Rev. Stat. Chapter 376). In support, AbbVie alleges as follows:

## PRELIMINARY STATEMENT

1. AbbVie brings this lawsuit to challenge the constitutionality of S.B. 751, seeking to amend Chapter 376 of the Revised Statutes of Missouri. This statute effects an unconstitutional taking under both the United States and Missouri Constitutions, violates the supremacy of United States federal laws by impermissibly adding state-law requirements for participating in the federal drug discount program established under Section 340B of the Public Health Service Act (the "340B statute"), and violates the Constitution's dormant Commerce Clause powers where it seeks to regulate purely out-of-state transactions.

2. The federal 340B statute establishes a comprehensive program that is designed to help uninsured and low-income patients gain better access to prescription medications at discounted prices. As a condition of participating in the federal Medicaid program, participating pharmaceutical manufacturers must offer their covered outpatient drugs at deeply discounted prices to an enumerated list of "covered entities"—certain registered and specially identified safety net hospitals and clinics—that are expected to serve vulnerable patient populations. *See* 42 U.S.C. § 256b(a)(4). Federal law thus imposes an obligation on manufacturers to provide their drugs at

[1] Available at https://www.senate.mo.gov/24info/BTS_Web/Bill.aspx?SessionType=r&BillID=186.

340B discounted prices to certain specified covered entities in exchange for the federal government's commitment to subsidize Medicaid beneficiaries' drug expenses. Contract pharmacies are not mentioned in—let alone required by—the federal 340B statute.

3. The federal statute grants the Secretary of the U.S. Department of Health and Human Services ("HHS") exclusive authority to enforce its provisions. *See* 42 U.S.C. § 256b(d). The statute leaves no role for states or other third parties to change the requirements of the federal 340B program or the conditions it imposes on manufacturers in return for participating in Medicaid. Nor do states or other third parties have any authority to enforce the federal statute's requirements. The Supreme Court has held that third-party enforcement "would undermine the agency's efforts to administer" the 340B program and other related federal programs "harmoniously and uniformly." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 119–20 (2011).

4. Because forcing manufacturers to transfer their drugs at discounted prices to covered entities raises serious constitutional concerns, Congress carefully limited the program to ensure that manufacturers' discounted drugs would be used to help needy patients and enacted certain safeguards to prevent the program from being abused for the benefit of other private parties. For example, in a statutory provision designed to prevent "diversion," Congress made clear that covered entities are not allowed to transfer manufacturers' drugs to anyone other than their own patients, prohibiting other entities from either participating in the 340B program or profiting from the sale of manufacturers' drugs at the 340B discounted price. *See* 42 U.S.C. § 256b(a)(5)(B).

5. Nevertheless, over the last decade, covered entities have entered into novel contractual arrangements with commercial pharmacies (called "contract pharmacies") that have allowed those pharmacies to profit from the sale of manufacturers' drugs. Instead of serving the

covered entities' uninsured and low-income patients, the for-profit contract pharmacies acquire manufacturers' drugs at the federally discounted price, sell them to patients (including indigent patients) at full price, and pocket the difference. Contract pharmacies accomplish this arbitrage through a complicated accounting system known as the "replenishment model," described in more detail below. The bottom-line result is that for-profit commercial pharmacies and the covered entities they contract with are able to pocket billions of dollars every year, splitting the profits at the expense of both manufacturers and the needy patients who are supposed to be served by the federal 340B program.

6. Neither contract pharmacies nor the replenishment model are features of the ordinary commercial drug-distribution system in the United States. Outside the 340B context, where they are unauthorized by statute, AbbVie has encountered no other commercial arrangement using contract pharmacies or the replenishment model. Contract pharmacies and the replenishment model are creatures only of the federal 340B drug discount arbitrage regime.

7. In response to these abuses, manufacturers (including AbbVie) have adopted policies that limit when they will sell or facilitate the transfer of drugs at the 340B discounted price to third-party commercial pharmacies. These policies recognize that the federal statute requires only that manufacturers "offer" their drugs at discounted prices to the covered entities *themselves*. There is no additional requirement that manufacturers provide 340B-discounted drugs to whomever and wherever the covered entities may demand, and there is certainly no requirement that manufacturers allow commercial pharmacies to *profit* from the sale of their drugs at discounted prices under the federal 340B program.

8. Manufacturers' decisions to address these abuses resulted in litigation between manufacturers and HHS and, in early 2023, the U.S. Court of Appeals for the Third Circuit

confirmed that the manufacturers' policies are lawful and permitted under federal law. *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696 (3d Cir. 2023).

9. The Third Circuit held that while Congress required manufacturers to offer their covered outpatient drugs at discounted prices in return for participating in Medicaid, it did not impose any additional obligation on manufacturers to provide their drugs to third-party commercial pharmacies, or to otherwise support arbitrage of their charitable discounts. Commercial pharmacies are not covered entities, and they are not entitled to benefit from the federal 340B program or access manufacturers' drugs at the 340B discounted price. *See id.*

10. The U.S. Court of Appeals for the District of Columbia Circuit recently agreed with the Third Circuit's conclusion, holding that because "section 340B merely requires manufacturers to propose to sell covered drugs to covered entities at or below a specified monetary amount," the statute gives manufacturers freedom "to impose at least some delivery conditions." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024). And because conditions such as limiting provision to "a single contract pharmacy designated by the covered entity" in no way impair a manufacturer's offer to sell drugs at the 340B discounted price, the restrictions fall within the ambit of freedom manufacturers enjoy under the federal 340B statute. *Id.* at 463–64.

11. Numerous states participated in the Third Circuit and D.C. Circuit cases as *amici curiae*. Once these amici began to lose, many of those same states turned to their own legislatures to propose and implement legislation to reach their desired 340B outcomes and attempt to impose requirements under the federal 340B statute that Congress chose not to impose. S.B. 751 is an example of one such piece of legislation.

12. In particular, S.B. 751 seeks to change the requirements of when and to which entities manufacturers must provide 340B discounted drugs as a condition of participating in

Medicaid. *See* S.B. 751 (codified at Mo. Rev. Stat. § 376.414 (effective August 28, 2024)). The 340B program simply requires manufacturers to "offer each covered entity covered outpatient drugs." 42 U.S.C. § 256b(a)(1). But S.B. 751 makes it unlawful for manufacturers to "deny, restrict, or prohibit, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with, or otherwise authorized by, a covered entity to receive 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services." S.B. 751, § A(2); Mo. Rev. Stat. § 376.414.2. It effectively gives covered entities unfettered authority to take manufacturers' property for the benefit of private parties of their choice. This Court should enjoin Defendants from enforcing S.B. 751, or the as-codified Mo. Rev. Stat. § 376.414, against AbbVie's efforts to counteract contract pharmacies' abuse of the federal 340B program.

13. S.B. 751 violates both the United States and Missouri Constitutions and should be enjoined.

14. ***First***, S.B. 751 deprives manufacturers of property without due process of law and results in an impermissible taking under the Fifth Amendment of the U.S. Constitution and Article I, Section 28 of the Missouri Constitution. Under the Fifth Amendment, made applicable to the states through the Fourteenth Amendment, neither the federal government nor the states have any authority to force A-to-B transfers of private property for the benefit of private parties. *See Kelo v. City of New London*, 545 U.S. 469, 477 (2005) (explaining that "the sovereign may not take the property of A for the sole purpose of transferring it to another private party B, even though A is paid just compensation"). The Missouri Constitution affords no less protection to private property. It has always been the law in this state that private property may not be taken for a private use. *State ex rel. Penrose Inv. Co. v. McKelvey*, 256 S.W. 474, 478 (Mo. 1923) (J., Graves, concurring).

15. The federal government has defended the federal 340B statute on grounds that manufacturers are not being *forced* to transfer their property to for-profit pharmacies, but instead supposedly agreed to do so at the request of covered entities "voluntarily" in exchange for the benefit of participation in the federal Medicaid program.

16. To the extent that defense is available to the federal government, it is not available to Missouri. S.B. 751 offers no voluntary exchange to manufacturers for compliance with Missouri's law, yet it purports to directly require manufacturers to transfer their property to "a pharmacy that is under contract with, or otherwise authorized by, a covered entity to receive 340B drugs on behalf of the covered entity." Mo. Rev. Stat. § 376.414.2. Missouri has no authority to take private property for private use, and no authority to deprive AbbVie of its property without due process of law. By seeking to change the requirements for when drug manufacturers must provide 340B price drugs to contract pharmacies at the request of covered entities, the statute unlawfully appropriates private property for the private benefit of commercial pharmacies and does so without serving any valid public purpose. *See Horne v. Dep't of Agric.*, 576 U.S. 350, 370 (2015) (holding government's confiscation of portion of farmers' raisin crop for charitable or other purpose without just compensation was a *per se* taking).

17. ***Second***, S.B. 751 is preempted by federal law under the Supremacy Clause. "Under the Supremacy Clause of the Federal Constitution, . . . any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield." *Felder v. Casey*, 487 U.S. 131, 138 (1988) (internal quotations omitted). By seeking to change the requirements of when and to which entities manufacturers must offer drugs at a discounted price as a condition of participating in the federal Medicaid program, S.B. 751 unlawfully modifies the requirements of the federal 340B program. Missouri's law impermissibly injects the Missouri

Attorney General and Missouri Board of Pharmacy into what Congress intended to be an exclusively federal scheme. S.B. 751. And, the law also conflicts with the objectives of the 340B statute, imposing requirements on drug manufacturers that conflict with the actual requirements of the federal 340B statute, thereby raising the costs of Medicaid participation above those set by Congress and deterring manufacturers from that participation.

18. ***Third***, S.B. 751 violates the Constitution's dormant Commerce Clause. The broad reach of Missouri's law encompasses transactions taking place wholly outside of and without relation to Missouri, extending to virtually every pharmaceutical manufacturer and pharmacy in the country. Where a state law purports to "directly regulate out-of-state transactions by those with no connection to the state," it violates the Constitution's commerce clause. *Nat'l Pork Prods. Council v. Ross*, 598 U.S. 356, 376 n.1 (2023).

19. AbbVie seeks a declaration that Missouri's S.B. 751 is unconstitutional because it effects an unconstitutional taking, is preempted by federal law, or violates the Constitution's dormant Commerce Clause by purposely seeking to regulate extraterritorial transactions. AbbVie further seeks injunctive relief barring the Missouri Attorney General and Missouri Board of Pharmacy from enforcing S.B. 751 against AbbVie.

## PARTIES TO THE ACTION

20. AbbVie, Inc., a Delaware Corporation, is a global research-based biopharmaceutical company dedicated to addressing some of the world's most complex and serious diseases, and advancing medical science in areas such as immunology, oncology, and neuroscience. Since 2012, AbbVie, Inc. has participated in the federal 340B drug discount program, helping uninsured and vulnerable patients obtain access to the medications they need. AbbVie's headquarters are located in North Chicago, Illinois. AbbVie, Inc. is a signatory to 340B

Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HHS's Health Resources and Services Administration ("HRSA").

21. Allergan, Inc., a Delaware Corporation, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340 Pharmaceutical Pricing Agreements, with HRSA.

22. Durata Therapeutics, Inc., a Delaware Corporation, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

23. AbbVie Products LLC, a Georgia Limited Liability Company, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

24. Aptalis Pharma US, Inc., a Delaware Corporation, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

25. Pharmacyclics LLC, a Delaware Limited Liability Company, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

26. Previously, Warner Chilcott Corporation merged with Allergan Sales, LLC and Allergan Sales, LLC is the surviving entity. Allergan Sales, LLC, a Delaware Limited Liability Company, is a signatory to 340B Pharmaceutical Pricing Agreements, and/or is successor-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

27. Defendant Andrew Bailey is the Attorney General of the State of Missouri. In that role, he has the responsibility and authority to enforce the laws of the state, including S.B. 751. Subsection 3 of S.B. 751 makes any violation of subsection 2 of the Act an unlawful practice under the Missouri Merchandising Practices Act ("MMPA"), Mo. Rev. Stat. § 407.020, and authorizes several "action[s]" permitted under the MMPA, including enforcement actions by the Attorney General for violations of the MMPA, *e.g.,* Mo. Rev. Stat. §§ 407.095, 407.100. This suit is brought against him solely in his official capacity.

28. Defendant James L. Gray is the President of the Missouri Board of Pharmacy, defendant Christian S. Tadrus is the Vice-President of the Missouri Board of Pharmacy, and defendants Douglas R. Lang, Anita K. Parran, Colby Grove, Tammy Thompson, and Darren Harris are Members of the Missouri Board of Pharmacy. This suit is brought against these individuals solely in their official capacities. S.B. 751 vests the Board with the responsibility and authority to "investigate any complaint of a violation of subsection 2 of [S.B. 751] by an individual or entity licensed by the board of pharmacy, and to impose discipline, suspension, or revocation of the license of any such individual or entity." Mo. Rev. Stat. § 376.414.4. S.B. 751 further gives the Board the authority to "promulgate rules to implement the provisions of subsection 2 of" S.B. 751. Mo. Rev. Stat. § 376.414.5.

**JURISDICTION AND VENUE**

29. AbbVie's causes of action arise under 28 U.S.C. § 1331, 42 U.S.C. § 1983, and the United States Constitution and the Constitution of the State of Missouri.

30. The Court has subject matter jurisdiction under 28 U.S.C. § 1331 and 28 U.S.C. § 1343(a)(3).

31. The Court has authority to grant injunctive and declaratory relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, and the Court's inherent equitable powers,

including the power to enjoin the actions of state officials if contrary to the United States Constitution or federal law. *See Ex parte Young*, 209 U.S. 123, 159–60 (1908).

32. Venue is proper in this district under 28 U.S.C. § 1391(b) because this action challenges a Missouri law that may otherwise apply to AbbVie's sale and provision of drugs at 340B-discounted prices under the federal 340B statute within this district. AbbVie provides drugs to multiple 340B covered entities within this District, and these entities purport to maintain contract pharmacy arrangements. Venue is also proper because the Missouri Attorney General maintains an office in St. Louis, MO in the Eastern Division of this District through which he could potentially enforce the challenged law. Similarly, a majority of the members of the Missouri Board of Pharmacy reside in this district. Defendants James L. Gray—the Board's President—and Douglas R. Lang reside in St. Louis, MO in the Eastern Division of this District; defendant Christian S. Tadrus—the Board's Vice-President—resides in Moberly, MO (Randolph County); and defendant Darren Harris resides in Kennett, MO (Dunklin County).[2]

## GENERAL ALLEGATIONS

### A. The 340B Drug Pricing Program

33. This case concerns section 340B of the federal Public Health Service Act, which created the federal "340B program" as part of the authority granted in the Veterans Health Care Act of 1992. *See* 42 U.S.C. § 256b; *see also* Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (1992).

34. The purpose of the federal 340B program is to "reduce pharmaceutical costs for safety-net medical providers and the indigent populations they serve" by creating "a low-cost

[2] *See* Missouri Division of Professional Registration, Board of Pharmacy, *Board Members*, https://pr.mo.gov/pharmacists-board-members.asp.

source of pharmaceutical medication for the indigent patients themselves." Connor J. Baer, *Drugs for the Indigent: A Proposal to Revise the 340B Drug Pricing Program*, 57 Wm. & Mary L. Rev. 637, 638 (2015) (footnote omitted).

35. Before Congress created the 340B program, individual manufacturers voluntarily provided their drugs at reduced prices to institutions that served needy and vulnerable patients. In 1990, Congress passed a statute called the Medicaid Rebate Act, which had the unintended consequence of creating disincentives for manufacturers to continue providing those voluntary discounts. H.R. Rep. No. 102-384, pt. 2, at 9–10 (1992). Through the Veterans Health Care Act, Congress remedied that unintended disincentive and established the federal 340B program, turning the manufacturers' previous voluntary support into a federal mandate.

36. The 340B statute requires that any manufacturer that participates in the federal Medicaid Drug Rebate Program must "offer" its covered outpatient drugs "for purchase" at deeply discounted prices to eligible "covered entities, which are" disproportionate share hospitals and other service providers that are expected to serve predominantly low-income and vulnerable patients. 42 U.S.C. § 256b(a)(1). The statute expressly limits participation in the 340B program to "covered entities." *See* 42 U.S.C. § 256b(a)(4). The statute defines "covered entities" to include only organizations that predominantly serve low-income patients. The definition includes, for example, federally qualified health centers, children's hospitals, qualifying rural hospitals, and clinics that serve vulnerable patients. *Id*. For-profit commercial pharmacies are not included in the statutory list of "covered entities." *Id*. § 256b(a)(4). Nor does the 340B statute include any provision authorizing covered entities to purchase manufacturers' drugs and dispense them through commercial pharmacies. *See AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 60 (D. Del. 2021) ("It is hard to believe that Congress enumerated 15 types of covered entities with a

high degree of precision and intended to include contract pharmacies as a 16th option by implication."), *aff'd sub nom. Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 703 (3d Cir. 2023).

37. The discounted 340B price for each of the manufacturer's drugs is calculated by subtracting the drug's Medicaid unit rebate amount from its Average Manufacturer Price, as determined under the federal Medicaid Drug Rebate Program, codified at section 1927 of the Social Security Act. *Id.* § 256b(a)(1)–(2) & (b). The resulting prices, called the 340B "ceiling prices," are significantly lower than the prices at which manufacturers sell their products to other purchasers. For the vast majority of innovator drugs, the mandatory discounts range from at least 23.1% to more than 99.9% of the average price in the market. *See* 42 U.S.C. § 1396r-8(c); 42 U.S.C. § 256b(a)(1). Many mandatory 340B ceiling prices are as little as one penny per unit of drug.

38. To indicate their agreement to participate in the federal 340B program and comply with its requirements, manufacturers sign a form contract with HHS, called the Pharmaceutical Pricing Agreement. That agreement is drafted by HHS. It has "no negotiable terms," and it "incorporate[s] the statutory obligations and record[s] the manufacturers' agreement to abide by them." *Astra*, 563 U.S. at 117–18.

39. The Pharmaceutical Pricing Agreement imposes no obligation on participating manufacturers to sell discounted drugs to contract pharmacies. Nor does the Pharmaceutical Pricing Agreement require manufacturers to cause their discounted drugs to be transferred to contract pharmacies. Nor does it grant covered entities any right to obtain access to manufacturers' drugs at discounted prices through contract pharmacies.

40. Both the Pharmaceutical Pricing Agreement and the federal 340B statute are structured to prevent commercial parties from participating in the federal 340B program or

profiting from the sale of manufacturers' drugs at discounted prices. Over the past decade, however, that is exactly what has happened as a result of covered entities entering into contractual relationships with commercial pharmacies. Under these arrangements, instead of using manufacturers' deeply discounted drugs to treat the indigent and uninsured patients that visit a covered entity and receive healthcare services from the covered entity itself, commercial contract pharmacies sell manufacturers drugs at regular prices to pharmacy customers and then demand that their stocks be replenished with drugs purchased by the covered entity through the federal 340B program at discounted prices, pocketing the difference (the "spread") for their own financial benefit.

41. In recent years, commercial contract pharmacies have earned annually over $3.3 *billion* in "spread." *See* Eric Percher et al., Nephron Research LLC, *The 340B Program Reaches a Tipping Point: Sizing Profit Flows and Potential Disruption* (2020) (concluding that $3.348 billion in 340B discounts were retained as profit by contract pharmacies in 2020 alone).

42. These abuses of the federal 340B program raise obvious concerns because the U.S. Constitution prohibits the government from forcing the transfer of property at confiscatory prices to private parties for their own private benefit. *See* U.S. Const. amend. V. They also violate both the letter and spirit of the federal 340B statute. Congress designed the 340B statute with the intent that there would be a close nexus between the federal discount drug pricing program and its only valid public purpose—helping low-income and uninsured patients obtain access to medications at discounted prices. Consistent with that intent, the statute prevents covered entities from using manufacturers' drugs to generate commercial profits or letting the drugs be transferred or sold to benefit entities outside the program.

43. The statute expressly forbids "diversion" by prohibiting covered entities from selling or otherwise transferring any manufacturer's discounted drugs "to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B) ("With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity").

44. The statute also prohibits covered entities from receiving or causing "duplicate discounts or rebates." They may not obtain a 340B discount and cause a Medicaid rebate to be paid by the manufacturer for the same unit of drug. *Id*. § 256(a)(5)(A).

45. The statute imposes an affirmative duty on the Secretary of HHS—through authority delegated to HRSA—to protect the program's integrity by "provid[ing] for improvements in compliance by covered entities . . . in order to prevent diversion" and violations of the statute's duplicate discount prohibition. *Id.* § 256b(d)(2)(A).

46. The statute provides mechanisms for resolving administrative disputes between manufacturers and covered entities through audits and a federal Administrative Dispute Resolution ("ADR") process. *See* 42 U.S.C. § 256b(d)(l)(B)(v), (d)(3). Notably, HRSA recently issued a final rule setting forth additional details of the congressionally prescribed 340B ADR process. *See* 89 Fed. Reg. 28643. The final rule established a comprehensive scheme to resolve disputes between manufacturers and covered entities arising under the 340B statute. Under the rule, a "340B ADR Panel" within HRSA is tasked with resolving not only disputes about drug prices but also "claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B"—the exact issue S.B. 751 seeks to address. *See* 42 C.F.R. §§ 10.3, 10.21; *accord id.* § 10.22(c)(1) ("A manufacturer is responsible for obtaining relevant information or documents from any wholesaler or other third party that facilitate the sale or

distribution of its drugs to covered entities."); 89 Fed. Reg. 28649 (April 19, 2024) ("HHS agrees and has further modified § 10.21(a)(1) to further explain that an overcharge claim generally includes claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price."); *id.* at 28644 ("[T]he 340B Program is related to drug pricing and drug distribution.").

47. The statute entrusts enforcement of the 340B statute *exclusively* to the Secretary of HHS and details what penalties may apply. *See* 42 U.S.C. § 256b(a)(5)(C)–(D), (d)(l)(B)(v), (d)(3). As the Supreme Court reasoned in *Astra*, Congress made HHS administrator of both the Medicaid Drug Rebate Program and the 340B program, and private enforcement by covered entities "would undermine the [HHS's] efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Astra*, 563 U.S. at 119–20.

48. The 340B statute provides no private right of action to covered entities. *Id.* at 113–14.

49. Failure to comply with the statutory requirements under the 340B program may result in termination of the Pharmaceutical Pricing Agreement (and the manufacturer's ability to participate in Medicaid), federal enforcement actions, and potentially the imposition of large civil penalties. *See id.* § 256b(a)(5)(D), (d)(1)(B)(vi), (d)(3)(A).

**B. The Growth in Contract Pharmacy Arrangements**

50. In 1996, HRSA issued non-binding guidance stating that the agency would not prevent covered entities *that lacked an in-house pharmacy* from entering into a contractual relationship with a *single* outside pharmacy to dispense covered outpatient drugs to the covered entity's patients. 61 Fed. Reg. 43,549 (Aug. 23, 1996). The guidance made clear that it "create[d] no new law and create[d] no new rights or duties." *Id.* at 43,550.

51. Guidance documents, such as the 1996 guidelines, are by definition general statements of policy that are non-binding, non-enforceable, and do not create any legal rights or obligations. They are intended instead to inform the public as to how HRSA intends to exercise its enforcement discretion.

52. In 2010, HRSA issued new non-binding guidance that radically changed how covered entities operated under the 340B program. The guidance stated, for the first time, that the agency would allow covered entities to enter into contractual relationships with an *unlimited* number of "contract pharmacies," even if the covered entity had an in-house pharmacy of its own. 74 Fed. Reg. 10,272 (Mar. 5, 2010).

53. Like the 1996 guidance, the 2010 guidance did not impose binding obligations on manufacturers. Indeed, HRSA again made clear that the non-binding guidance created no new rights and imposed no new obligations. *See id.* at 10,273 ("This guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law"). In other words, while HRSA indicated that it would not interpret the 340B statute to prohibit covered entities from using multiple contract pharmacies, it did not purport to impose any obligation on manufacturers to transfer drugs to contract pharmacies or otherwise facilitate covered entities' use of contract pharmacies.

54. Following issuance of the 2010 guidance, covered entities dramatically increased their use of contract pharmacies, with a recent study reporting an increase of 4,228% between 2010 and 2020. This explosion in the use of contract pharmacies has been driven by the prospect of sharing in the outsized profit margins on manufacturer-subsidized 340B drugs. For example, in

2009 340B drug sales totaled just $4.2 billion, but by 2023 had increased by more than 30-fold to $124 billion.[3]

55. Similarly, the number of covered entities participating in the program jumped from around 15,000 in 2010 to more than 50,000 by 2020.[4]

56. Nor does the program's explosive growth correlate with an increase in indigent patients, or improvements in care. Indeed, since 2010, the percentage of uninsured patients in the United States has fallen by nearly 38%.[5]

57. Contract pharmacies, which are predominantly large commercial pharmacy chains, do not operate like in-house pharmacies, do not themselves qualify as covered entities, and do not owe fiduciary duties to the covered entities. The relationships between covered entities and the for-profit, commercial pharmacies are governed by arm's-length contracts. Contract pharmacies are not "agents" of the covered entities; they are merely business partners. Importantly, these arrangements do not exist outside the context of the federal 340B program, as there is no other context in which commercial pharmacies are able to share in the "spread" generated by selling manufacturers' discounted drugs to their customers at full prices.

58. Contract pharmacy arrangements generally use one of two inventory models: (1) pre-purchased inventory or (2) replenishment.

59. A few contract pharmacies use the pre-purchased inventory model, in which a covered entity's 340B purchased drugs are kept in stock at the contract pharmacy, and when filling

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3 Karen Mulligan, USC Schaeffer Cntr., White Paper: The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments, at 5 (Oct. 2021); Rory Martin & Harish Karne, IQVIA, White Paper: The 340B Drug Discount Program Grew to $124B in 2023, at 2 (2024).

4 Mulligan, White Paper *supra* note 2 at 4.

5 *See* Kenneth Finegold et al., HHS APSE Off. Of Health Pol'y, No. HP-2021-02, Issue Brief: Trends in the U.S. Uninsured Population, 2010-2020, at 2 (Feb. 11, 2021).

prescriptions on behalf of that covered entity, the contract pharmacy uses the covered entity's 340B purchased inventory.

60. Most contract pharmacies, however, use what is known as the "replenishment" model. Under the replenishment model, no 340B purchased drugs are kept in stock at the contract pharmacy. Instead, the contract pharmacy fills all prescriptions using its own non-340B purchased inventory (that is, full price inventory)—including those prescriptions issued by covered entities. After a sufficient quantity of a particular drug is dispensed, the covered entity orders additional quantities of that drug at the federal 340B price be transferred to the contract pharmacy to "replenish" the non-340B drugs dispensed by the contract pharmacy on the covered entity's behalf. *See* Declaration of RADM Krista M. Pedley, Director, Office of Pharmacy Affairs, HRSA, *Eli Lilly & Co. v. Becerra*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind.), ECF No. 125-2 at ¶¶ 3–11.

61. Instead, they carry out 340B determination at the back end, well after a drug has been dispensed (and likely consumed) by the patient. Pharmacies first purchase AbbVie products for their general inventories at regular prices. After a particular quantity of a particular drug is dispensed to pharmacy customers, the pharmacy, either itself or through a third-party administrator ("TPA") with which it contracts, retroactively determines which prior dispensing events should be linked with 340B eligibility. Based on that determination, they then instruct covered entities—or sometimes even without going through a covered entity—to place orders for drugs at the discounted 340B price to "replenish" their general inventories to make up for the higher, regular prices they paid at the beginning.

62. In other words, under the replenishment model, contract pharmacies do not keep a separate inventory of 340B drugs but instead dispense drugs to both 340B and non-340B patients alike out of their general inventories. Nor do most contract pharmacies attempt to determine prior

to or at the point of sale whether the patient is eligible for a 340B discounted drug. In almost all instances, contract pharmacies order AbbVie-manufactured drugs and dispense them to their customers at full price without knowledge as to whether, at the time of dispensing, that patient is a 340B-eligible patient.

63. For-profit pharmacies purchase AbbVie products for their general inventories at market prices. After a particular quantity of a particular drug is dispensed to pharmacy customers, the pharmacy, either itself or through a third-party administrator ("TPA") with which it contracts, determines which prior dispensing events should be linked with 340B eligibility. This determination is based on the contract pharmacy's own criteria, without any involvement from the covered entities. If those criteria are designed correctly, the post-sale determination may be able to calculate how many 340B drugs AbbVie must sell. But in reality, the contract pharmacies' criteria often include prior patients, who no longer receive the 340B discounted drugs at the pharmacy but are included under a "once-a-patient-always-a-patient" approach, so the covered entity and its pharmacies are able to maximize the arbitrage profits from the 340B program. As the D.C. Circuit observed, "[t]he covered entity, the pharmacy, and the third-party administrator often divvy up the spread between the discounted price and the higher insurance reimbursement rate. Each of these actors thus has a financial incentive to catalog as many prescriptions as possible as eligible for the discount." *Novartis*, 102 F.4th at 457–58.

64. At the same time as they use their own distorted criteria to mark otherwise 340B-ineligible sales as deserving the federally mandated low prices, contract pharmacies (typically through a TPA) instruct covered entities—sometimes even without going through a covered entity—to place orders of additional quantities of drugs at the discounted 340B price to "replenish" their general inventories that they will use to supply non-340B eligible sales. Significantly, as a

result of such replenishment, contract pharmacies take title to the drugs they purchase from manufacturers, either through covered entities or on their own behalf. At no point in time does a covered entity take title to the drugs under this model. *See Sanofi Sues HHS, HRSA for Contract Details Between Covered Entities, Contract Pharmacies*, 340B Report (June 18, 2024) (according to a covered entity spokesperson, "in order for the replenishment model to work, 'the title to 340B drugs transfers to the contract pharmacy at the time it is taken into inventory.'"). AbbVie is also not aware of any instance where a contract pharmacy or covered entity represents that an agency relationship exists between them such that the contract pharmacy acts at the direction of a principal covered entity.

65. In practice, therefore covered entities and contract pharmacies share in the "spread" generated by selling the drugs at higher prices to pharmacy customers and/or seeking full commercial reimbursement from the patients' insurance plans. For-profit, commercial pharmacies thereby obtain significant profits from selling the 340B covered outpatient drugs that manufacturers must offer to covered entities at deeply discounted prices.

66. By dramatically expanding the pool of individuals who can access the discounted drugs that covered entities can buy at discounted prices—including individuals who do not qualify as patients of the covered entity—covered entities and commercial pharmacies can obtain profits that extend far beyond Congress's intent when it created the 340B program. One study found that in 2018 alone, covered entities and their contract pharmacies generated more than $13 billion in estimated gross profits from the purchase of manufacturers' drugs at mandated 340B prices.

67. When commercial pharmacies are brought into the program, there is a significantly greater risk that manufacturers' discounted drugs will be dispensed to individuals who are not "patients" of the covered entity. As HHS has found, contract pharmacy arrangements "create

complications in preventing diversion" (for example, contract pharmacies cannot verify patient eligibility in real-time like a covered entity can). HHS Office of Inspector General, OEI-05-13-00431, Mem. Report: Contract Pharmacy Arrangements in the 340B Program (2014) ("HHS Report"), at 1.

68. Because contract pharmacies often dispense 340B covered outpatient drugs from the same inventory as drugs dispensed to all other customers (and seek replenishment after the fact), the opportunities for unlawful distributions to ineligible patients increases, allowing covered entities and contract pharmacies to profit from the diversion that Congress intended to prohibit. *See* GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836, at 28 (Sept. 2011) (noting that "approximately two-thirds of diversion findings in HRSA audits involved drugs distributed at contract pharmacies"); GAO, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480, at 35, 43–44 (June 2018) (finding 45% of covered entities that responded to a recent GAO survey admitted they do not provide any discount to patients who use their contract pharmacies; and many of the remaining 55% reported rarely giving discounts to patients obtaining medicines through contract pharmacies).

69. Covered entities and commercial pharmacies reap windfalls from gaining access to manufacturers' drugs at deeply discounted prices under the federal 340B program, but uninsured and underinsured patients are not benefitting. *See* HHS Report, at 2 (finding that "some covered entities in our study do not offer the discounted 340B price to uninsured patients at their contract pharmacies"); Adam J. Fein, *The Federal Program that Keeps Insulin Prices High*, Wall. St. J. (Sept. 10, 2020) (explaining that "almost half the U.S. pharmacy industry now profits from the 340B program, which is designed as a narrow support to certain hospitals," while patients "don't

benefit," even though manufacturers have "practically given the product away"); IQVIA Study, at 12 ("The 340B Drug Discount Program as it exists today is a complex system of arbitrage . . . in which most vulnerable patients at contract pharmacies do not get drug discounts."); Lin JK, et al., *Assessment of US Pharmacies Contracted with Health Care Institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Characteristics*, JAMA Health Forum (2022), at 2 (finding that contract pharmacy growth from 2011–2019 was concentrated in affluent and predominantly White neighborhoods and that the share of 340B pharmacies in socioeconomically disadvantaged and primarily non-Hispanic Black and Hispanic/Latino neighborhoods declined).

70. For example, the North Carolina Department of the State Treasurer published a recent report explaining that "some hospitals are using the 340B program to enrich themselves rather than to serve vulnerable communities," and "instead . . . expanded into wealthier neighborhoods with a higher percentage of insured individuals who pay more for the drugs." N.C. Dep't of State Treasurer, N.C. State Health Plan, Overcharged: State Employees, Cancer Drugs, and the 340B Drug Pricing Program, at 3.

71. While commercial pharmacies are driving massive growth in the 340B program—at double-digit annual rates—charity care by hospitals has decreased. Commentators have noted, for example, that as the 340B program has grown at a remarkable rate, the total value of hospitals' uncompensated care has significantly declined. *See* Letter from Adam J. Fein to Hon. Lamar Alexander and Hon. Greg Walden in response to request for input on 340B drug pricing program (Oct. 30, 2020); Adam J. Fein, *340B Program Purchases Reach $24.2 Billion—7%+ of the Pharma Market—As Hospitals' Charity Care Flatlines*, Drug Channels (May 14, 2019).

72. Both the New York Times and Wall Street Journal have run exposés describing the flaws in contract pharmacy arrangements, flaws that enable arbitrage and damage the very

communities that the federal 340B program was designed to help. *See* Katie Thomas & Jessica Silver-Greenberg, *Profits Over Patients: How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, NY Times (Sept. 24, 2022) (describing how one 340B hospital "has been slashing services at Richmond Community while investing in the city's wealthier, white neighborhoods, according to more than 20 former executives, doctors and nurses"); Anne Wilde Mathews et al., *Many Hospitals Get Big Drug Discounts. That Doesn't Mean Markdowns for Patients.*, Wall Street Journal (Dec. 22, 2022) ("The data show that hospitals often extend their 340B discounts to clinics in well-off communities, where they can charge privately insured patients more than those on Medicaid" which "raise questions about the program's growth and purpose").

**C. Manufacturers' Response to HRSA's Overreach**

73. AbbVie and other manufacturers have exercised their lawful right to decline covered entity requests that manufacturers provide their discounted 340B drugs to an unlimited number of commercial pharmacies.

74. AbbVie has implemented initiatives making clear that it will not indiscriminately accept requests that it transfer 340B discounted drugs to an unlimited number of third-party commercial contract pharmacies servicing hospital covered entities.

75. As 340B abuse continued to grow, with covered entities purporting to require manufacturers to provide 340B drugs to an excessive number of for-profit pharmacies—sometimes located more than 100 miles from the covered entity's location—AbbVie updated its policy to place reasonable limits around provision to contract pharmacies. Specifically, if a covered entity has its own in-house pharmacy, AbbVie's policy is to only take orders for direct delivery to the in-house pharmacy. However, if a covered entity does not have an in-house pharmacy capable of dispensing to outpatients, it is permitted to designate one contract pharmacy located within 40

miles of the HRSA registered covered entity parent site. AbbVie will facilitate bill to/ship to orders of 340B priced medicines to that location, but to prevent 340B abuse, the covered entity must submit limited claims data on 340B utilization for such contract pharmacy location. In implementing its initiatives, AbbVie confirmed that it will continue to offer "each covered entity" the ability to "purchase" its covered outpatient drugs "at or below the applicable ceiling" price set by statute. 42 U.S.C. § 256b(a)(1).

76. AbbVie is committed to ensuring that each hospital covered entity has at least one pharmacy location where it can receive shipments of discounted AbbVie medicines, and out of which it can dispense AbbVie's discounted 340B drugs to qualifying patients. If a hospital covered entity is unable to identify an eligible contract pharmacy within 40 miles, AbbVie will work with the covered entity to identify a suitable alternative.

77. In addition to AbbVie, many other pharmaceutical manufacturers have adopted policies directed at addressing abuses of the 340B program by covered entities and contract pharmacies. Like AbbVie's, these policies do not refuse to supply drugs at discounted prices under the federal 340B program solely because the covered entity has an arrangement with a number of contract pharmacies; instead, they are directed at addressing program abuses.

78. AbbVie's policy is not only consistent with those upheld by the Third and D.C. Circuits but also gives covered entities and contract pharmacies more convenience at its own expense. *See Sanofi Aventis*, 58 F.4th at 701; *Novartis*, 102 F.4th at 463–64. Despite these benefits and Circuit court decisions authorizing such policies, AbbVie has suspended or will suspend its contract pharmacy policy in Missouri and come into compliance with Mo. Rev. Stat. § 376.414.

79. AbbVie's compelled compliance is directly attributable to Missouri's enactment of Mo. Rev. Stat. § 376.414, which is set to come into effect August 28, 2024. Should this Court find

S.B. 751 (or Mo. Rev. Stat. § 376.414 as codified) unconstitutional, AbbVie is prepared to promptly resume implementation of its contract pharmacy policy in Missouri.

**D. Litigation in Federal Courts**

80. HHS initially recognized that it lacked authority to compel manufacturers to transfer drugs to contract pharmacies. *See* Tom Mirga, HRSA Says Its 340B Contract Pharmacy Guidance Is Not Legally Enforceable, 340B Report (July 9, 2020). HHS then reversed its position and attempted to impose a new obligation on manufacturers.

81. On December 30, 2020, HHS issued a final decision—labeled an "Advisory Opinion"—that for the first time ever purported to require manufacturers to facilitate the transfer of their products to for-profit commercial pharmacies. *See* HHS, Advisory Opinion No. 20-06, Contract Pharmacies Under the 340B Program (Dec. 30, 2020). Various manufacturers brought suit in early 2021 to challenge this HHS decision.

82. On May 17, 2021, the government sent certain manufacturers "compliance" letters purporting to enforce the 340B statute, which stated that HHS had made a final determination that AbbVie had violated the 340B statute by not agreeing to transfer 340B discounted drugs to unlimited contract pharmacies.

83. While the December 30 decision was later withdrawn following a ruling from the federal district court for the district of Delaware, *see AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47 (D. Del. 2021), the May 2021 letters were not withdrawn.

84. On January 30, 2023, the Third Circuit issued a decision recognizing that Congress intentionally "chose not to" impose delivery-related obligations on manufacturers, explaining that the federal 340B statute's plain text suggests that Congress intended "one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies." *See Sanofi Aventis*, 2023 WL 1098017, at *4.

85. The Third Circuit further found that manufacturers' policies do not prevent covered entities from participating in the 340B program or entering into contractual relationships with commercial pharmacies. Under manufacturers' policies, covered entities "can still buy and dispense unlimited discounted drugs by having them delivered to an in-house or contract pharmacy." *Id*.

86. The Third Circuit rejected the argument that manufacturers were not permitted to address program abuses, such as diversion and duplicate discounting, by imposing restrictions on when they will transfer drugs to commercial pharmacies.

87. On May 21, 2024, the D.C. Circuit issued its own opinion endorsing the same view, holding that "section 340B merely requires manufacturers to propose to sell covered drugs to covered entities at or below a specified monetary amount." *Novartis*, 102 F.4th at 460. As a result, as long as a manufacturer's policy "neither precludes [it] from making a bona fide 'offer' nor increases its contract 'price'"—such as only "deliver[ing] section 340B drugs to a covered entity's in-house pharmacy or to a single contract pharmacy designated by the covered entity"—the condition is legitimate and may be enforced without running afoul of 340B. *Id.* at 463–64.

88. The Eighth Circuit Court of Appeals recently upheld a state contract pharmacy law in Arkansas because the Court concluded that "[c]overed entities maintain title to the 340B drugs," and the "pharmacy becomes an agent of the covered entity." *Pharma. Res. & Manfs. of Am. v. McClain*, 95 F.4th 1136, 1142, 1144 (8th Cir. 2024). That is not true in Missouri. Covered entities do not maintain title to 340B-discounted drugs provided to contract pharmacies, nor do contract pharmacies serve as the "agent of the covered entity."

**E. The Missouri Law**

89. While the federal courts were deciding that the federal 340B statute grants manufacturers the freedom to adopt policies to combat abuse of the 340B program by contract

pharmacies, Missouri turned to its own legislature to enact a law that purports to take that freedom away. To that end, the Missouri legislature passed S.B. 751 and delivered it to the Governor Michael L. Parson for signature On May 30, 2024.

90. On July 11, 2024, Governor Parson declined to sign or veto S.B. 751, meaning the bill became law without signature and will take effect August 28, 2024. In a letter explaining his decision, Governor Parson acknowledged "the General Assembly's intent to improve patient access and affordability," but explained that "the 340B program" and S.B. 751 are "flawed." He noted that S.B. 751 "ensures the expansion of a flawed federal program within the state of Missouri," which, according to the Governor, may come with a "concern[ing] . . . impact." "Most troubling," from the Governor's perspective, is that "the 340B program at large lacks requirements for cost savings to be passed onto patients and further lacks transparency as to how cost savings are used." He asserts that S.B. 751 "***fails to address*** those concerns, but places strict restrictions on pharmaceutical manufacturers' ability to deny, restrict, or prohibit the acquisition of 340B-priced drugs by pharmacies that are contracted with or authorized by covered entities under the program."

91. The Governor criticized S.B. 751 for "inhibit[ing]" the 340B "program's structure"—which "is a product of federal law and regulations"—"by placing limitations on how program participation is managed." In his view, "[t]he use of contract pharmacies by covered entities under the program—among other programmatic concerns—is an issue that should be addressed by Congress."[6] In other words, S.B. 751 raises serious constitutional concerns and does not effectively address the issues it was drafted to solve.

[6] Governor Michael L. Parson, *Letter to the Secretary of State of the State of Missouri Regarding Senate Bill 751* (July 11, 2024),

92. As Governor Parson suggested, the text of S.B. 751 makes clear that changing the terms of the federal 340B program is its regulatory object. The bill defines the terms "340B drug" and "covered entity" by referencing 42 U.S.C. § 256b, the federal 340B statute. *See* Mo. Rev. Stat. §§ 376.414.1(1), (2). In other words, the Missouri statute cannot exist except in the context of the federal 340B program.

93. Missouri's law directly eliminates manufacturers' ability to adopt policies to prevent 340B abuse or prevent the taking of their own property by entities not otherwise entitled to it: "A pharmaceutical manufacturer . . . shall not deny, restrict, or prohibit, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with, or otherwise authorized by, a covered entity to receive 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services." *Id.* § 376.414.2.

94. Subsection 3 of S.B. 751 makes any violation of subsection 2 of the Act an unlawful practice under the Missouri Merchandising Practices Act ("MMPA"), Mo. Rev. Stat. § 407.020, and authorizes "any action" permitted in "Mo. Rev. Stat. § 407.010 to 407.130." Mo. Rev. Stat. § 376.414.3. And "[e]ach package of 340B drugs determined to be subject to a prohibited act under subsection 2 of [S.B. 751] . . . constitute[s] a separate violation under subsection 2 . . . ." *Id.* "Package" is defined as "the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product." *Id.* § 376.414.1(3) (incorporating by reference 21 U.S.C. § 360eee(11)(A)).

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https://content.govdelivery.com/attachments/MOGOV/2024/07/11/file_attachments/2934538/SB%20751%20NR.pdf.

95. Among other actions, the MMPA authorizes the Attorney General of Missouri to (1) issue to those who he believes violated or are "about to" violate the MMPA "an order prohibiting" their conduct, or (2) "seek and obtain, in an action in a circuit court, an injunction," "temporary restraining orders, preliminary injunctions, temporary receivers, and the sequestering of any funds or accounts" against such violators or would-be violators. *See* Mo. Rev. Stat. §§ 407.095, 407.100. The Attorney General may also "petition for recovery of civil penalties" "of not more than five thousand dollars per violation" against "[a]ny person who violates the terms of an injunction, an order to make restitution, or any other judgment or order issued under section 407.100." *Id.* § 407.110.

96. In addition, S.B. 751 authorizes the "state board of pharmacy . . . to investigate any complaint of a violation of subsection 2 of [S.B. 751] by an individual or entity licensed by the board of pharmacy, and to impose discipline, suspension, or revocation of the license of any such individual or entity." *Id.* § 376.414.4. S.B. 751 further gives the Board the authority to "promulgate rules to implement the provisions of subsection 2 of" S.B. 751. *Id.* § 376.414.5.

97. The statute cites no source, under the 340B statute or elsewhere, that permits Missouri to add requirements to the conditions for participating in the federal 340B program, or that authorizes Missouri to establish an enforcement process for the Attorney General or Missouri Board of Pharmacy to seek remedies for alleged violations of the federal 340B requirements.

98. S.B. 751 purports to limit its scope, forbidding certain manufacturer conduct "unless such receipt is prohibited by the United States Department of Health and Human Services." *Id.* § 376.414.2. It further states that "[n]othing in [S.B. 751] shall be construed or applied to be less restrictive than any federal law as to any person or entity regulated by this section." *Id.* § 376.414.6. It also provides that "[n]othing in [S.B. 751] shall be construed or applied to be in

conflict with any of the following: (1) Applicable federal law and related regulation; or (2) Other laws of this state, if the state law is compatible with applicable federal law." *Id.* Finally, it states that "[l]imited distribution of a drug required under 76 U.S.C. Section 355-1 shall not be construed as a violation 77 of subsection 2 of this section." *Id.* § 376.414.7.

99. Despite stating that it should not be construed to conflict with federal law, there is no way to read S.B. 751 in congruence with the 340B statute. There is no role for states to regulate 340B pricing and the distribution of 340B priced drugs to entities permitted as a matter of federal law to participate in the federal program and obtain access to manufacturers' drugs at discounted prices. The specific provisions of S.B. 751 conflict with Section 340B's requirements for drug manufacturers as well as its enforcement and penalty scheme.

**STANDING**

100. AbbVie is injured by S.B. 751 because the law forces AbbVie to provide its private property to another private party in a prohibited A-to-B wealth transfer and for no recognized public use or purpose. Once taken, AbbVie's property is not recoverable, nor is there any easy way to "undo" the 340B-discount once applied and provided to contract pharmacies. Moreover, the law subjects AbbVie to potential enforcement by the Missouri Attorney General and Missouri Board of Pharmacy. Plaintiffs are signatories to 340B Pharmaceutical Pricing Agreements, and/or are successors-in-interest to executed 340B Pharmaceutical Pricing Agreements, with HRSA.

101. AbbVie's injuries are fairly traceable to S.B. 751 because the statute compels a private transfer of AbbVie's 340-discounted drugs to private, for-profit commercial pharmacies. There is no recognized public use or purpose for such a transfer. That transfer would not occur but-for the operation of S.B. 751's prohibition on AbbVie's contract pharmacy policy. In addition, the law seeks to impose new state law obligations on drug manufacturers participating in the 340B

program beyond those required by the federal statute. Neither section 340B, nor any existing regulation, nor the Pharmaceutical Pricing Agreement, contains these requirements.

102. A favorable ruling is likely to address AbbVie's injuries. Enjoining the provisions of S.B. 751 that apply to pharmaceutical manufacturers and unconstitutionally force the taking of their private property for no public use would redress AbbVie's injuries because AbbVie's property would not be unconstitutionally taken, nor would it be forced to comply (or continue complying) with a preempted and unconstitutional law.

**BASIS FOR INJUNCTIVE RELIEF**

103. "Irreparable harm occurs when a party has no adequate remedy at law, typically because its injuries cannot be fully compensated through an award of damages." *Facility Guidelines Inst., Inc. v. UpCodes, Inc.*, 677 F. Supp. 3d 955, 975 (E.D. Mo. 2023) (quoting *Gen. Motors Corp. v. Harry Brown's, LLC*, 563 F.3d 312, 319 (8th Cir. 2009)). Moreover, where costs are not recoverable because the government-defendant enjoys sovereign immunity from monetary damages, irreparable harm generally exists. *See Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2489 (2021) ("The moratorium [on collecting rent during COVID-10 pandemic] has put the applicants, along with millions of landlords across the country, at risk of irreparable harm by depriving them of rent payments with no guarantee of eventual recovery."); *see also Iowa Utls. Bd. v. FCC*, 109 F.3d 418, 426 (8th Cir. 1996) ("The threat of unrecoverable economic loss . . . does qualify as irreparable harm.").

104. Effecting an unconstitutional taking of AbbVie's private property in a forced transfer to another private party for no recognized public use or purpose constitutes an irreparable injury. *See Laclede Gas Co. v. St. Charles Cnty.*, 713 F.3d 413, 419–20 (8th Cir. 2013) (affirming grant of preliminary injunction on takings claim).

105. Moreover, if S.B. 751 is not enjoined as applied to AbbVie, AbbVie would be exposed to additional state law requirements as a condition of participating in the federal 340B program and would risk violating S.B. 751 simply by performing its federally mandated functions. *See Brooks v. Francis Howell Sch. Dist.*, 599 F. Supp. 3d 795, 805 (E.D. Mo. 2022) ("Well-settled law holds that the loss of [constitutional] freedoms, even for minimal periods of time, 'unquestionably constitutes irreparable injury.'" (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976))). A party may be irreparably injured in the face of the threatened enforcement of a preempted law. *See, e.g.*, *Craig v. Simon*, 980 F.3d 614, 617–18 (8th Cir. 2020); *see also Bank One, Utah v. Guttau*, 190 F.3d 844, 847–48 (8th Cir. 1999) (concluding that where the plaintiff proves preemption and "that it will suffer irreparable harm if the State is not enjoined from enforcing [the preempted law], then the question of harm to the State and the matter of the public interest drop from the case, for [the plaintiff] will be entitled to injunctive relief no matter what the harm to the State, and the public interest will perforce be served by enjoining the enforcement of the invalid provisions of state law."); *Rogers Grp., Inc. v. City of Fayetteville*, 629 F.3d 784, 785, 789–90 (8th Cir. 2010) (affirming preliminary injunction in preenforcement suit alleging that a municipality's ordinance was beyond its powers under state law and finding a sufficient threat of irreparable harm where the plaintiff "admit[ted] that the Quarry currently operated at a level the Ordinance permitted" but "testified that the Ordinance would prevent the Quarry from expanding"); *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 160 (2014) (concluding that a plaintiff has standing to "bring a preenforcement suit when he has alleged an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder." (internal quotation marks and citation omitted)); *Ass'n for Accessible Medicines v. Ellison*, 2023 WL 8374586, at *6–7 (D. Minn. Dec.

4, 2023) (granting motion for preliminary injunction when the statute at issue was already in effect and movants were in compliance).

106. If drug manufacturers such as AbbVie are required to provide their drugs to an unlimited number of contract pharmacies, the magnitude of the economic loss is beyond the capacity of Missouri to compensate with damages. Discounted purchases under the program reached approximately $44 billion for fiscal year 2021. *See* HRSA, 2021 340B Covered Entity Purchases, https://www.hrsa.gov/opa/updates/2021-340B-covered-entity-purchases. Missouri's June 30, 2024 "All Funds" Financial Summary indicates that it received a total of about $52.881 billion in receipts and transfers and spent about $52.820 billion in the trailing twelve months, leaving only about a $61.296 million surplus.[7] The ordinary legal remedy of damages would be insufficient to cover AbbVie's losses. *See Eastern Enters. v. Apfel*, 524 U.S. 498, 521 (1998) (plurality op.) (noting that the Supreme Court has considered injunctive relief where there is a "lack of a compensatory remedy").

107. Prospective injunctive relief is appropriate because of the ongoing nature of the infringement of constitutional rights resulting from S.B. 751. The law effects a repeated and ongoing mandatory private wealth transfer of AbbVie's 340B-discounted drugs to private, for-profit commercial pharmacies for the private benefit of that pharmacy and for no recognized public use, in violation of the United States' Constitution. A taking occurs each and every time a drug manufacturer is required against its own volition to transfer its drugs at the 340B discount price to a commercial pharmacy for the private benefit of that pharmacy. In addition to depriving AbbVie and other manufacturers of their property as a matter of law, the law deprives AbbVie and others

[7] *See* Missouri Office of Administration (Division of Accounting), *State of Missouri Receipts, Expenditures, and Transfers – All Funds* (June 30, 2024), https://acct.oa.mo.gov/media/report/financial-summary-all-funds-june-30-2024 (listed amounts are rounded to the nearest million).

of their federal rights under the actual terms of the 340B program. The deprivation of constitutional rights constitutes irreparable injury for purposes of an injunction. *Planned Parenthood of Minn., Inc. v. Cit. for Community Action*, 558 F.2d 861, 867 (8th Cir. 1977) (citing Wright & Miller, Federal Practice and Procedure § 2948 (1973)); *see also Nichols v. Moyers*, 2013 WL 2418218, at *2 (E.D. Mo. June 3, 2013) ("[Plaintiff's] ongoing inability to exercise her fundamental [constitutional] right . . . shows that she is threatened with irreparable harm in the absence of injunctive relief."); Wright & Miller, Federal Practice and Procedure § 2948.1 n. 26 (2d ed. 1995) (collecting cases).

108. Granting injunctive relief here would not harm Missouri. It is well settled that a state "cannot be irreparably harmed by an inability to enforce an unconstitutional law." *Toigo v. Dep't of Health & Senior Servs.*, 549 F. Supp. 3d 985, 995 (W.D. Mo. 2021); *Rodgers v. Bryant*, 942 F.3d 451, 458 (8th Cir. 2019) (upholding the lower court's "imposition of a . . . preliminary injunction" where it found, among other things, that "preventing [a state] from enforcing a law that is plainly unconstitutional would cause no injury." (internal quotation marks omitted)); *Pavek v. Simon*, 467 F. Supp. 3d 718, 762 (D. Minn. 2020) ("[A] State has no interest in enforcing laws that are unconstitutional and an injunction preventing the State from enforcing the challenged [unconstitutional] statute does not irreparably harm the State." (internal quotation marks and citation omitted) (cleaned up)); *Hispanic Interest Coalition of Ala. v. Governor of Alabama*, 691 F.3d 1236, 1249 (11th Cir. 2012). Moreover, there is no evidence that uninsured and needy patients—in Missouri or anywhere else—benefit from the use of contract pharmacies, and Missouri has no legitimate interest in enriching commercial pharmacies at the expense of manufacturers and patients.

109. Granting injunctive relief would be in the public interest. The public has no legitimate interest in enforcing unconstitutional laws, particularly those that force a private property transfer for no public use or purpose. *See Fernandez v. St. Louis Cnty., Missouri*, 538 F. Supp. 3d 888, 903 (E.D. Mo. 2021) ("The public has no interest in enforcing an unconstitutional ordinance." (internal quotation marks and citation omitted)). By contrast, the public has a strong interest in preventing states from imposing unconstitutional requirements that force the transfer of private property for the private benefit of private commercial parties. *Nichols*, 2013 WL 2418218, at *2 ("[T]he Eighth Circuit has made clear that 'it is always in the public interest to protect constitutional rights.'" (quoting *Phelps–Roper v. Nixon*, 545 F.3d 685, 690 (8th Cir.2008))). Further, the public has a strong interest in enforcing federal law and not permitting states to change the requirements for participation in federal healthcare programs.

**FIRST CLAIM FOR RELIEF**

***Prospective Injunctive Relief and Declaratory Relief – Violation of Takings Clause, U.S. Const. amend. V, cl. 4***

110. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

111. The Takings Clause of the Fifth Amendment provides: "[N]or shall private property be taken for public use, without just compensation." U.S. Const. amend V.; *see also Chicago, Burlington & Quincy Ry. v. Chicago*, 166 U.S. 226 (1897) (incorporating and making applicable to states the Takings Clause of the Fifth Amendment through the Due Process Clause of the Fourteenth Amendment).

112. The Takings Clause extends to both real and personal property. *Horne v. Dep't of Agric.*, 576 U.S. 350, 358 (2015). It is not limited to instances when the government physically appropriates property for its own use through eminent domain. A taking can also occur through

legislation and regulation that sufficiently deprives a user of its property rights. *See E. Enters. v. Apfel*, 524 U.S. 498, 529 (1998).

113. Under the Constitution, the government has no authority to force A-to-B transfers of private property for the benefit of private parties. *See Kelo v. City of New London*, 545 U.S. 469, 477 (2005) (explaining that "the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation"). Such private takings are always unconstitutional, since "[n]o amount of compensation can authorize such action." *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 543 (2005); *Calder v. Bull*, 3 U.S. (3 Dall.) 386, 388 (1798) ("[i]t is against all reason and justice" to allow government to "take[] property from A. and give[] it to B").

114. "Whenever a regulation results in a physical appropriation of property, a per se taking has occurred." *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2072 (2021). Statutes or regulations that mandate the physical transfer of personal property from one private party to another private party amount to an unconstitutional taking with or without just compensation.

115. S.B. 751, as codified at Mo. Rev. Stat. § 376.414, appropriates AbbVie's property rights in its drugs for the private benefit of for-profit, commercial pharmacies. If Missouri requires manufacturers to provide their drugs to other private entities at below-market prices—by purporting to add that as a state-law obligation attached to the federal 340B scheme—then Missouri is engaged in an impermissible *per se* violation of the Constitution's Takings and Due Process Clauses.

116. In the alternative, Missouri effectuates a partial regulatory taking.

117. In *Penn. Central Transportation Corp. v. New York City*, 438 U.S. 104, 124 (1978), the Supreme Court recognized that a regulatory taking requires consideration of a flexible three-

factor test: (1) the economic impact of the regulation, (2) the extent to which the regulation has interfered with investment backed expectations, and (3) the "character of the governmental action."

118. S.B. 751's purported requirement that manufacturers transfer their drugs to commercial pharmacies is constitutionally impermissible because it requires the physical acquisition of AbbVie's drugs by another private party for no public purpose or use; imposes significant financial losses on AbbVie and other manufacturers; interferes with drug manufacturers' reasonable investment backed expectations; and serves no valid government purpose because it deprives manufacturers of the full use and control of their property on a continual basis for the commercial benefit of private parties.

**SECOND CLAIM FOR RELIEF**

***Prospective Injunctive Relief and Declaratory Relief – Violation of Takings Clause, Mo. Const. art. I, § 28***

119. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

120. The Missouri Constitution, like the federal Constitution, prohibits A-to-B transfers of private property for the benefit of private parties. Mo. Const. art. I, § 28 ("That private property shall not be taken for private use with or without compensation, unless by consent of the owner, except for private ways of necessity, and except for drains and ditches across the lands of others for agricultural and sanitary purposes, in the manner prescribed by law . . . ."); *Labrayere v. Bohr Farms, LLC*, 458 S.W.3d 319, 329 (Mo. 2015) ("[A]rticle I, section 28 [of the Missouri Constitution] . . . categorically bars the state from taking property for private uses."); *City of Kansas City v. Hon*, 972 S.W.2d 407, 409 (Mo. Ct. App. 1998) ("Eminent domain cannot be used by the State to involuntarily take private property for private use.").

121. In the alternative, Missouri has also engaged in a regulatory taking under the Missouri Constitution by "'go[ing] too far' in restricting the exercise of [AbbVie]'s property rights." *Labrayere v. Bohr Farms, LLC*, 458 S.W.3d 319, 329 n.6 (Mo. 2015) ("A regulatory taking occurs when a government regulation does not result in a physical invasion of property or the denial of all economically viable use but, instead, 'goes too far' in restricting the exercise of property rights."). "Property is defined as including not only ownership and possession but also the right of use and enjoyment for lawful purposes." *Hoffmann v. Kinealy*, 389 S.W.2d 745, 752 (Mo. banc 1965). "The state constitutional provisions barring the taking of private property apply equally to the enjoyment and the possession of lands." *Labrayere*, 458 S.W.3d at 329 (internal quotation marks and citations omitted). "Consequently, an arbitrary interference by the government, or by its authority, with the reasonable enjoyment of private lands is a taking of private property without due process of law, which is inhibited by the Constitution." *Id.* (internal quotation marks and citations omitted). For the same reasons outlined above, S.B. 751 also effectuates an unconstitutional taking under the Missouri Constitution.

**THIRD CLAIM FOR RELIEF**

***Federal Preemption Under the Supremacy Clause, U.S. Const. art. VI, cl. 2***

122. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

123. Under the Supremacy Clause of the Constitution, federal law is "supreme . . . , any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. As a result, federal statutes and regulations properly enacted and promulgated can nullify or "override[] a [conflicting] state law" or local actions. *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 353 (2000). In other words, "where a state statute conflicts with, or frustrates,

federal law, the former must give way." *Forest Park II v. Hadley*, 336 F.3d 724, 731-33 (8th Cir. 2003) (cleaned up) (concluding that the remedy plaintiff requested for a violation of state law "would be legally unwarranted if the state statutes are preempted"); *Oberkramer v. IBEW-NECA Serv. Ctr.*, 151 F.3d 752, 756 (8th Cir. 1988) (concluding the district court properly dismissed state common law claims which were preempted by federal law).

124. Preemption can take multiple forms: express preemption, field preemption, and conflict preemption. *Forest Park II*, 336 F.3d at 732.

125. Field preemption occurs when Congress "occupies an entire field" of regulation so comprehensively that it has "foreclose[d] any state regulation in the area, even if it is parallel to federal standards." *Arizona v. United States*, 567 U.S. 387, 401 (2012); *see also Crosby*, 530 U.S. at 372-73. Field preemption also occurs where Congress intends "to foreclose any state regulation in the area, even if it is parallel to federal standards." *Arizona*, 567 U.S. at 401.

126. The 340B program is a comprehensive federal healthcare program. Every detail of the 340B program is determined by federal law, including which entities are eligible to participate in the program and the consequences for participating manufacturers who fail to comply with the 340B statute's requirements. The statute does not authorize state regulation concerning 340B pricing and who is entitled to access manufacturers' drugs at discounted 340B prices. It leaves no room for states to interfere with the carefully designed 340B program.

127. It is foundational constitutional law that States may not use their police power to regulate Congress's creations. *See McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 159 (1819) (Marshall, C.J.). A state law may not change the conditions for participation in the federal Medicare and Medicaid programs. Any attempt by Missouri to regulate in this area impermissibly

changes the requirements for participating in the federal 340B program and nullifies the "natural effect" of federal law. *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372–73 (2000).

128. Conflict preemption occurs where it is impossible for a private party to comply with both state and federal law and also where "the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby*, 530 U.S. at 372–73; *see also Forest Park II*, 336 F.3d at 733.

129. Congress tasked neither the Attorney General of Missouri nor the Missouri Board of Pharmacy with enforcement of the 340B statute. "Congress . . . made HHS administrator of the interdependent Medicaid Rebate Program and 340B Program." *Astra USA, Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. 110, 120 (2011). State enforcement "would undermine the agency's efforts to administer these two programs harmoniously and uniformly." *Id.*

130. Congress not only defined who was entitled to administer the 340B program (the Secretary of HHS, who has lawfully delegated the authority to HRSA), it also delineated which tools were available to the Secretary to ensure compliance. The 340B statute defines which audit procedures and ADR mechanisms are available under the 340B program for handling disputes among manufacturers and covered entities concerning program compliance. *See* 42 U.S.C. § 256b(d)(l )(B)(v), (d)(3). Likewise, Congress outlined the penalties that apply to manufacturers who violate the statutory requirements under the 340B program and engage in "overcharging." *See* 42 U.S.C. § 256b(d)(l)(B)(vi), (d)(2)(B)(v). S.B. 751's attempts to install an alternative compliance regime conflict with the procedures detailed in the 340B statute and the lawfully promulgated federal rules implementing the statute.

131. Missouri also has no lawful authority to force manufacturers to transfer their drugs under the 340B program at deeply discounted prices to any entity, let alone commercial pharmacies

that do not qualify as covered entities under the program. The carefully delineated obligation for manufacturers to offer 340B priced drugs to covered entities is lawfully imposed by federal law solely as a condition of a manufacturer's participation in federal healthcare programs. To the extent that Missouri seeks to impose, through S.B. 751, any substantive obligation on manufacturers beyond what federal law requires, that state law obligation is preempted by federal law.

**FOURTH CLAIM FOR RELIEF**

***Declaratory/Injunctive Relief – Dormant Commerce Clause***

132. AbbVie re-alleges and incorporates by reference all of the allegations contained in the preceding paragraphs of this complaint as though set forth fully herein.

133. S.B. 751 runs afoul of the Constitution's Dormant Commerce Clause because it purports to "directly regulate out-of-state transactions by those with *no* connection to the state." *Nat'l Pork Prods. Council v. Ross*, 598 U.S. 356, 376 n.1 (2023); *see also Ass'n for Accessible Medicines v. Frosh*, 887 F.3d 664 (4th Cir. 2018) (striking down a Maryland law that could be triggered by "a transaction that did not result in a single pill being shipped to Maryland" and had the potential to effect purely out-of-state commerce).

134. S.B. 751 forces "pharmaceutical manufacturer[s]" to deliver 340B drugs to any "pharmacy that is under contract with, or otherwise authorized by, a covered entity to receive 340B drugs on behalf of the covered entity." Mo. Rev. Stat. § 376.414.2.

135. S.B. 751 defines "covered entity" by referencing the definition for the term in the federal 340B statute, 42 U.S.C. § 256b(a)(4), which does not limit the scope of such entities to those in any state, let alone Missouri. *See* Mo. Rev. Stat. §§ 376.414.1(2).

136. Similarly, S.B. 751 defines "pharmacy" by referencing Mo. Rev. Stat. § 338.210, which defines the term as "***any location*** where the practice of pharmacy occurs or such activities

are offered or provided by a pharmacist or another acting under the supervision and authority of a pharmacist." *See* Mo. Rev. Stat. §§ 376.414.1(5).

137. Finally, S.B. 751 defines "pharmaceutical manufacturer" as "an entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of covered outpatient drugs, whether directly or indirectly, by extraction from substances of natural origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of covered outpatient drugs." *Id.* at § 376.414.1(4). This definition does not limit the scope of "pharmaceutical manufacturer[s]" to those operating within the state of Missouri.

138. Through this series of definitions, S.B. 751 allows a pharmacy in "any location" to direct manufacturers in any location to deliver 340B drugs to any location of their choice and places no restriction whatsoever on where such location must be. In other words, Missouri's law extends not just to pharmaceutical manufacturers, covered entities, and contract pharmacies located within Missouri, but to virtually every manufacturer, covered entity, and pharmacy in the country. Missouri's law could govern a transaction between a drug manufacturer located in Illinois, its wholesaler in Kentucky, and a California contract pharmacy that dispenses the drug to a Texas resident. Such broad reach violates the United States Constitution's prohibition under the Dormant Commerce Clause.

## PRAYER FOR RELIEF

**WHEREFORE,** AbbVie prays for the following relief:

a. A declaration, order, and judgment declaring that S.B. 751 effects an impermissible taking of AbbVie's property for private benefit;

b. A declaration, order, and judgment holding S.B. 751 unlawful because it is preempted by federal law and unconstitutional under the Supremacy Clause;

c. A declaration, order, and judgment declaring that S.B. 751 violates the dormant Commerce Clause of the United States Constitution;

d. A declaration, order, and judgment holding that the 340B statute does not require drug manufacturers to provide 340B pricing to contract pharmacies or transfer or cause their discounted covered outpatient drugs to be transferred to contract pharmacies;

e. A preliminary and permanent injunction enjoining the Missouri Attorney General and Missouri Board of Pharmacy from enforcing S.B. 751;

f. An award of all costs and attorneys' fees pursuant to any applicable statute or authority; and

g. Any other relief that this Court deems just and proper.

Dated: July 22, 2024

Respectfully submitted,

*/s/ Robert T. Haar*

Robert T. Haar (MO#3044)
Lisa A. Pake (MO#39397)
HAAR & WOODS, LLP
1010 Market St., Suite 1620
St. Louis, MO 63101
Telephone: (314) 241-2224
Email: roberthaar@haar-woods.com
lpake@haar-woods.com

AND

Matthew S. Owen, P.C. (*pro hac vice* forthcoming)
Meredith M. Pohl (*pro hac vice* forthcoming)
Michael A. Pronin (*pro hac vice* forthcoming)
KIRKLAND & ELLIS LLP
1301 Pennsylvania Avenue N.W.
Washington, D.C. 20004
Telephone: (202) 389-5000

Ashley C. Parrish (*pro hac vice* forthcoming)
John D. Shakow (*pro hac vice* forthcoming)
KING & SPALDING LLP
1700 Pennsylvania Avenue N.W.
Suite 900
Washington, D.C. 20006
Telephone: (202) 626-2627
Email: aparrish@kslaw.com

Nicole Bronnimann (*pro hac vice* forthcoming)
KING & SPALDING LLP
1100 Louisiana, Suite 4100
Houston, TX 77002
Telephone: (713) 276-7402
Email: nbronnimann@kslaw.com

Email: matt.owen@kirkland.com
meredith.pohl@kirkland.com
michael.pronin@kirkland.com

*Counsel for Plaintiffs.*